

## REMARKS/ARGUMENTS

Claims 28, 29, 31, 33, 34, 38, and 39 have been amended. Claims 28-39 remain pending upon entry of this amendment.

Claims 28, 29, 33, 34, 38, and 39 have been amended to recite that the Sp1 or B segment-binding  $\beta_3$ -adrenergic receptor ( $\beta_3$ -AR) *trans*-activating factor is human. Support for this amendment can be found throughout the specification and in particular on page 48, line 21 - page 51, line 2; page 55, line 17 - page 56, line 22; and page 57, line 28 - page 58, line 26.

Claims 28, 29, 33, 34, 38, and 39 have been amended to recite that “A method of screening for a compound ... in mammalian cells, which method comprises: (a) contacting mammalian cells ....” Support for these amendments can be found throughout the specification and in particular on page 27, lines 16-17 and page 29 lines 11-25.

Claim 31 has been amended to delete the phrase “express at very low level.” No new matter has been added by way of these amendments.

## Rejections under 35 U.S.C. § 112, first paragraph- written description

Claims 28-39 have been rejected for allegedly failing to fulfill the written description requirement. Specifically, the Examiner alleges that the claims encompass an Sp1 or B segment-binding  $\beta_3$ -AR *trans*-activating factor obtained from literally any source, and that this broad genus of such transcription factors must be predictive of how the human proteins in human cells will respond to a given test compound.

Applicants respectfully disagree with this rejection. However, in order to advance the prosecution of this application, the pending independent claims (claims 28, 29, 33, 34, 38, and 39) have been amended to recite that the Sp1 or B segment-binding  $\beta_3$ -adrenergic receptor ( $\beta_3$ -AR) *trans*-activating factor is human. Accordingly, it is believed that this rejection has been obviated and Applicants respectfully request its withdrawal.

**Rejections under 35 U.S.C. § 112, first paragraph- enablement**

Claims 28-39 have been rejected for alleged failure to fulfill the enablement requirement. The Examiner alleges that the claims encompass the use of non-human cells and the use of non-human Sp1 or B segment-binding  $\beta_3$ -AR *trans*-activating factors in an assay to determine the effects of test compound on human cells comprising Sp1 and/or B segment-binding  $\beta_3$ -AR *trans*-activating factors. Specifically, the Examiner alleges that although the specification is enabling for embodiments where the cells contacted in the assay produce human Sp1 or B segment-binding  $\beta_3$ -AR *trans*-activating factor and wherein the contacted cells are human, the specification does not enable embodiments where the Sp1 or B segment-binding  $\beta_3$ -AR *trans*-activating factor is not human and where the assay cells are not human cells. The Examiner also alleges that the guidance and working examples in the specification are directed solely to the human proteins and assays done in human cells.

As described above, the pending independent claims (claims 28, 29, 33, 34, 38, and 39) have been amended to recite that the Sp1 or B segment-binding  $\beta_3$ -adrenergic receptor ( $\beta_3$ -AR) *trans*-activating factor is human.

AR) *trans*-activating factor is human. In addition, the claims have been amended to recite “A method of screening for a compound ... in mammalian cells, which method comprises: (a) contacting mammalian cells ....”

The specification describes and enables using any mammalian cell in the claimed methods. For example, page 27, lines 16-17 state:

Any mammalian cell can be used to screen for molecules that increase or decrease the activity of a  $\beta_3$ -AR *trans*-activating factor.

The specification also describes and enables examples of particular cell lines that could be used in the claimed assays (e.g. WAT cells, muscle cells, liver cells, HeLa cells, CV-1 cells, BAT cells and human neuroblastoma cells (see page 29 lines 11-25)). In addition, it is standard for one of ordinary skill in the art to test human proteins in non-human mammalian cells. In addition, the claims as amended now recite a method of screening for a compound that increases (or inhibits)  $\beta_3$ -AR *trans*-activating factor activity in mammalian cells. Thus, the claims no longer require that this method of screening be predictive of  $\beta_3$ -AR *trans*-activating factor activity in human cells.

It is believed that the claims as pending, which recite “A method of screening for a compound that increases activity of a human Sp1 or B segment-binding  $\beta_3$ -adrenergic receptor ( $\beta_3$ -AR) *trans*-activating factor in mammalian cells, which method comprises: (a) contacting mammalian cells ....,” are enabled and described by the present specification. Accordingly, it

is believed that this rejection has been obviated and Applicants respectfully request its withdrawal.

**Rejections under 35 U.S.C. § 112, second paragraph-indefiniteness**

Claim 31 has again been rejected as allegedly indefinite because of the phrase “express at very low level.” Specifically, the Examiner alleges that the specification does not provide an objective standard for what is a “very low” level expression of  $\beta_3$ -AR and he alleges that the specification does not put a quantifiable number on what would satisfy the “very low” limitation. The Examiner has suggested that this phase be deleted in order to obviate this rejection (see page 6 Action).

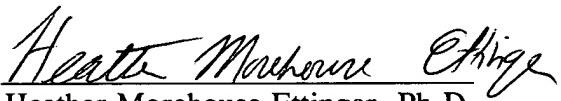
Without conceding the Examiner’s position, claim 31 has been amended to delete the phrase “express at very low level.” Accordingly, this rejection has been obviated and Applicants respectfully request its withdrawal.

**Conclusion**

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue.

If there are any other issues remaining which the Examiner believes could be resolved through either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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